



USDA Foreign Agricultural Service

GAIN Report

Global Agriculture Information Network

Template Version 2.09

Required Report - public distribution

Date: 11/21/2005

GAIN Report Number: CH5069

China, Peoples Republic of

Biotechnology

Agricultural Biotechnology Report

2005

Approved by:

Maurice House
U.S. Embassy Beijing

Prepared by:

Anthony Cino, Kevin Latner, Wu Bugang

Report Highlights:

Despite problems in transparency in the development of regulations combined with onerous testing requirement on imported biotechnology products, U.S. biotech soybeans and other products are selling at record highs and are forecasted to continue doing well in the future. It seems clear now that biotechnology will play an integral part of China's agricultural development in the next 20 years. China is currently the largest market for U.S. agricultural biotechnology products, is the fifth largest producer of biotechnologically enhanced plants based on total number of acres, and is developing a strong biotech research program. China is set to become an even larger player in agricultural biotechnology as it has just ratified the Biosafety Protocol. FAS Beijing continues to work with the Chinese government in this area and to push for increased transparency and overall market access for U.S. biotechnology crops.

Includes PSD Changes: No
Includes Trade Matrix: No
Unscheduled Report
Beijing [CH1]
[CH]

Table of Contents

SECTION I. EXECUTIVE SUMMARY	3
SECTION II. BIOTECHNOLOGY TRADE AND PRODUCTION.....	3
Biotechnology crop production in China	3
Biotechnology crop development in China	4
Importation of biotechnology crops	4
Food aid in China.....	5
Potential for agricultural biotechnology exports to the United States.....	5
SECTION III. BIOTECHNOLOGY POLICY.....	5
Regulatory framework of agricultural policy	5
Political factors and their effect on the biotech trade.....	7
Approved biotechnology products.....	8
Biotechnology products under field trials	13
Stacked events and simultaneous approvals	14
Labeling policy for biotechnology products.....	14
China and the Biosafety Protocol.....	14
Barriers to U.S. exports of biotechnology products.....	14
SECTION IV. MARKETING ISSUES.....	16
Market acceptance issues.....	16
SECTION V. CAPACITY BUILDING AND OUTREACH	16
U.S. Government funded outreach and capacity building programs	16
SECTION VI. REFERENCE MATERIALS	16
Reference Materials Subcategory	16

SECTION I. EXECUTIVE SUMMARY

China is the largest market for U.S. biotechnology crops. Despite problems in transparency in the development of regulations combined with onerous testing requirement on imported biotechnology products, U.S. biotech soybeans and other products are selling at record highs and are forecasted to continue doing well in the future.

The future of agricultural biotechnology policy in the People's Republic of China is still in some doubt, but it seems clear now that biotechnology will play an integral part of China's agricultural development in the next 20 years. China is currently the largest market for U.S. agricultural biotechnology products (predominantly imported soy beans and domestic cotton), is the fifth largest producer of biotechnologically enhanced plants based on total number of acres (3.7 million hectares in 2004), and is developing a strong biotech research program, spending over 363 million RMB (about \$44 million USD) in 2003, a threefold increase over 1998 expenditures. China is set to become an even larger player in agricultural biotechnology as it has just ratified the Biosafety Protocol.

While China has begun to accept more domestic and imported biotechnology products, significant barriers still exist for U.S. biotech products entering the market in China. These barriers include requirements that product be fully approved first from the originating country before application for approval in China, duplicative testing for products already approved in the United States, lack of regulatory framework to treat stacked events, and holding only two windows a year for acceptance of applications for new products.

Several internal and external factors seem to be influencing China's biotech policy. First, China has sought self-reliance in grains, adding pressure for new technologies to improve output. Bureaucratic competition seems to exist between the several ministries within the government over control of biotech policy. Trade concerns exist over countries like Japan and Korea who have threatened not to import rice and corn from China if it become a producer of biotech varieties. And finally, China has made food security and protection of domestic development of the biotech field a priority.

Several ministries are influential in biotechnology, however the Ministry of Agriculture is the country's primary governing body over agricultural biotechnology issues. Its Ministerial Decrees 8, 9 and 10 largely create the legal framework under which these products are regulated. Other government agencies, such as the General Administration on Quality Supervisions Inspection and Quarantine (AQSIQ), the Ministry of Health (MOH) and the State Environmental Protection Administration (SEPA) are also involved. SEPA is the leading agency on the Biosafety Protocol and has allegedly been working on new overarching regulations that would supercede the previous MOA decrees. There is no timeframe for the promulgation of these regulations.

FAS Beijing is working with the Chinese government to facilitate programs on building their capacity to better manage the biotechnology field. FAS Beijing also continues to push for increased transparency in the development of regulations governing this field and look for ways to promote overall market access for U.S. biotechnology crops.

SECTION II. BIOTECHNOLOGY TRADE AND PRODUCTION

Biotechnology crop production in China

China has commercialized four genetically modified plants since 1997, including cotton, tomato, sweet pepper and petunia, and China is now the fifth largest producer of agricultural biotechnology crops in the world by acreage (behind the United States, Argentina, Canada, and Brazil) at 3.7 million hectares in 2004. Pest-resistant cotton is the largest biotechnology enhanced product produced in China. The production area estimate for Bt cotton was 2.8

million hectares in 2003, which, according to a MOA survey, increased to 3.3 MHA in 2004/2005. The result is that about 60 percent of cotton produced in China is now Bt cotton, which is 8 percent higher than 2003. In the Yellow River Region, Bt varieties accounted for 95 percent, and the Yangtze River Region 70 percent. (CH5032)

There seems to be an indication that a certain level of commercial production occurs outside of official approvals and statistics. A survey started in 2002 at the Biochemical Analysis and Experiment Center of Ho Chi Minh Agricultural University found that although corn is not a biotech product that has been approved for commercial production, 30% of the corn sampled from China was in fact genetically modified. The imported GM corn mainly contained pest and herbicide resistant genes. (VM5050)

For a detailed list of agricultural biotechnology products approved for commercial production, see Section III.

Biotechnology crop development in China

China does not regularly publish lists on products undergoing development in China. Recent information from the Ministry of Science and Technology suggest that hundreds of events are undergoing testing. Generally, the Chinese government has made the advancement of the biotechnology field a high priority. China has the most sophisticated agricultural biotechnology program in the developing world.

There is no private sector development in China. Seeds in China are all produced by public research institutes and universities funded by the Chinese government. Outside investment in this field was possible until 2002 when such investment became illegal. In 2003, China's government spent over 363 million RMB (about \$44 million USD) on biotechnology research, three times 1998 funding levels.

China has developed several of its own transgenic grains, but none have been commercialized. China is most notably working on the development of a rice variety that is resistant to bacterial blight known as Xa21. This would be the first biotechnology enhanced rice to be produced in China. It is expected that China will use this first biotechnology rice product as a means of paving the way for more domestic product approvals.

China recently announced the approval of a new insect resistant GM cotton crop (YinMian 2). The crop allegedly can resist bollworms and media in China reports an increase in yield of 25%. China's Cotton Research Institute is using transgenic technology to breed new varieties of cotton with disease resistance and better fiber quality, but no detailed results were available yet and no varieties have been commercialized. (CH5032)

Importation of biotechnology crops

China has approved 4 biotech products for import, (soy beans, corn, canola, and cotton) and is becoming a significant importer of U.S. biotech products. In February of 2004 the Ministry of Agriculture granted safety certificates to the first round of genetically altered crops under the new regulations. Since that time, China has gone on to approve a series of biotechnology improved crops from the U.S. The most significant recent approval was Monsanto's NK603 corn. Due to China's strict customs regulations under AQSIQ Ministerial Decree 62, the U.S. was concerned that traces of biotech corn found in U.S. soy bean shipments would be grounds for China's denial of the shipments based on food safety. The approval of this corn variety has eased these concerns. The complete list to date of approved biotech imports is as follows.

Imported GMOs Approved for Processing Purposes				
Crop	Trait	Developer	Event	Validity
Soybeans	Herbicide tolerance	Monsanto	GTS40-3-2	2004-2007
Corn	Herbicide tolerance	Monsanto	GA21	2004-2007
Corn	Insect resistance	Monsanto	MON810	2004-2007
Cotton	Insect resistance	Monsanto	531	2004-2009
Cotton	Herbicide tolerance	Monsanto	1445	2004-2009
Corn	Insect resistance	Monsanto	MON863	2004-2007
Canola	Herbicide tolerance	Monsanto	GT73	2004-2007
Corn	Insect resistance and herbicide tolerance	Syngenta	Bt176	2004-2007
Corn	Insect resistance and herbicide tolerance	Syngenta	Bt11	2004-2007
Corn	Insect resistance and herbicide tolerance	Dupont /Dow Agrosciences	1507	2004-2007
Corn	Insect resistance and herbicide tolerance	Bayer CropScience	T25	2004-2007
Canola	Herbicide tolerance	Bayer CropScience	Ms1Rf1	2004-2007
Canola	Herbicide tolerance	Bayer CropScience	Ms1Rf2	2004-2007
Canola	Herbicide tolerance	Bayer CropScience	Ms8Rf3	2004-2007
Canola	Herbicide tolerance	Bayer CropScience	T45	2004-2007
Canola	Herbicide tolerance	Bayer CropScience	Topas19/2	2004-2007
Canola	Herbicide tolerance	Bayer CropScience	Oxy-235	2004-2007
Corn	Herbicide tolerance	Monsanto	NK603	2005-2008

Food aid in China

China is no longer a recipient of food aid. The final delivery of food aid from the World Food Program (WFP) was delivered to China in April of 2005 after 25 years of being an aid recipient. The WFP has determined that China can now afford to eliminate its areas of extreme poverty by itself.

Potential for agricultural biotechnology exports to the United States

China has produced and is producing several biotechnologically enhanced crops that have not yet passed through the U.S. regulatory system. See the list of commercialized crops for more details.

SECTION III. BIOTECHNOLOGY POLICY

Regulatory framework of agricultural policy

China's Ministry of Agriculture has been delegated the lead biotechnology agency in agriculture with several other agency's involvement, including China's General Administration on Quality and Supervision, Inspection and Quarantine (AQSIQ), China's State Environmental Protection Administration (SEPA), the Ministry of Science and Technology (MOST), the Ministry of Commerce (MOFCOM), and the Ministry of Health (MOH).

The biotechnology regulatory environment for agriculture outlined in the State Council's regulations *"Food and Agricultural Import Regulations and Standards; Agricultural Genetically Modified Organisms Safety Administration Regulations 2001"* (CH1056) is largely governed by MOA's implementing regulations, Ministerial Decrees 8, 9 and 10. These decrees: *Measures on the Safety Evaluation Administration of Agricultural GMOs, Measures on the*

Safety Evaluation Administration of Agricultural GMO Imports, and Measures on Agricultural GMO Labeling Administration (CH2002) cover domestic approval, import approval and labeling respectively.

Approval for domestic cultivation:

The approval process for biotechnology products involves five steps: research, pilot experiment, environmental release, experimental production, and safety certification. Safety certificates are issued by the MOA's Biosafety Office of Agricultural GMO, and are not good nationally and can only be used in the provinces it has been granted for. The Biosafety Office of Agricultural GMO delegates testing to the National Biosafety Committee. The following steps are taken exclusively for products that will undergo local development and cultivation.

(1) First the applicant must assemble the appropriate materials as outlined in Decree 8, including a report on experimental research the applicant has already undertaken. **(2)** After submitting the materials and review by MoA's Biosafety Office of Agricultural GMO, the applicant may begin "Medium testing," which are controlled tests at a small level in a controlled environment. **(3)** Upon completion of the test and passing the safety examination of the National Biosafety Committee, an application is made back to the Biosafety Office of Agricultural GMO to begin the next round of testing known as "environmental release." Environmental release is medium scale test in natural environment with specified safety precautions. **(4)** Upon completion of these tests and passing the safety examination of the National Biosafety Committee, an application is made back to the Biosafety Office of Agricultural GMO to begin the final round of testing known as "production testing." Production testing is large-scale testing conducted prior to final approval. **(5)** Finally, after passing the safety evaluation of the National Biosafety Committee, the applicant may apply to the Biosafety Office of Agricultural GMO for a safety certificate. Upon receipt of the application the Biosafety Office of Agricultural GMO will arrange for the National Biosafety Committee to conduct a safety evaluation. The applicant, upon passing the evaluation, is granted the safety certificate and is allowed to move on to the usual examinations, registrations, evaluations and approval formalities.

Importation into the China market:

Agricultural biotechnology products imported into China must be approved by the Ministry of Agriculture. The approval process varies depending on whether the product's intended use (research, production or as a raw material, which makes up all products on the table below) and on the safety level, rating the potential threat of the organism to health and the environment.

Generally, for importation of products for raw material, which consists of the bulk of exports from the U.S. to China, Article 12 of decree 9 states that foreign company must apply for an agricultural GMO safety certificate from the Biosafety Office of Agricultural GMO. The regulations require applicants to provide a variety of materials and to have certification that the exporting country has allowed use of products and sells them in its domestic market and that they have undergone tests there showing no harm to animals, plants and the ecological environment.

Again, different conditions apply depending on the use and nature of the product to be imported. Note that products imported for production must also go through the series of field test described in the section above. Importers are encouraged to consult these regulations in detail.

Import safety certificates are good for three years, and renewal can be initiated one year prior to their expiration. The safety certificates issued for the first phase of biotechnology product approvals under the new regulations are due to expire in 2007. The decision to

renew these and subsequent certificates will focus on changes in product use over the initial certification, whether intentional or not.

Labeling:

For labeling see the relevant section below.

Other Ministries:

China's State Environmental Protection Administration (SEPA) has the lead authority for the Biosafety Protocol, which China ratified on April 27, 2005, and thus is charged with developing implementing regulations. Though SEPA has not published any new or revised laws with regard to implementation of the Protocol, SEPA has continued to state its intent to develop an overarching Biosafety Law that would take precedence over the Ministry of Agriculture's decrees regulating agricultural biotechnology. SEPA has stated that work on the new biosafety law began 5 years ago and has been held up due to their importance and comprehensive nature.

Ministry of Science and Technology (MOST) has also been an active participant in the development of biotechnology policy and implementation. MOST also manages a large amount of central government funds that are distributed to Chinese institutes researching new strains of biotech seeds and foods.

The General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) is responsible for nation-wide management of the inspection and quarantine for entry and exit of all GMO products. AQSIQ's local entry and exit inspection and quarantine agencies are responsible for the inspection and quarantine of entry and exit GMO products within each jurisdiction. AQSIQ's Ministerial Decree 62 (CH4017) governs the steps that should be taken at customs when importing or exporting biotechnologically enhanced goods.

Political factors and their effect on the biotech trade

Factors influencing the development of biotech policy in China include:

Self-reliance: China's efforts over the last several years to become self-reliant on grain (official sources indicate self-reliant as being 85-90% self-sufficiency) have created pressure on the government to adopt more progressive biotechnology policies.

Bureaucratic Competition: Inter-agency struggles exist over the future of biotechnology policy in China. China's signing of the Biosafety Protocol and the need for new national regulations to bring itself into conformity with the Protocol have cast some doubts on who will take the country forward in this area. MoA largely regulates this area now, however SEPA (who is seen as more cautious on biotech issues) is said to be drafting the regulations to go with the Protocol. MOST (who has been a strong supporter of development of biotechnology in China) has also been influential in the development of policy.

Trade Concerns: There is uncertainty over the impact that further GM crop commercialization would have on Chinese agricultural exports. Although the country has become a net farm product importer in recent years, it is concerned about losing export markets for non-GM crops and food products. China exports corn and rice to Korea and Japan and both have said they will stop importing if China commercializes biotech varieties of these products.

Food Security: China continues to place great emphasis on food security and developing a domestic biotechnology capacity, and wants to insure the health of its biotechnology sector as it opens its market.

Thus while China develops biotech rice due to food security concerns, market concerns have lead to the prohibition on planting biotech soybeans. This prohibition against planting new soybean strands exists, despite the fact that RoundupReady Soybeans are cleared for import, so that China can maintain a "GMO Free" label when exporting Chinese soybeans to those European and Asian markets that restrict the import of biotech-derived foods. (CH5017) Thus policy makers are still struggling with competing interests.

In the policy realm, China has sent mixed signals to the global biotech industry and agricultural traders over the years. Having pursued a promotional approach in the mid-1980s, Beijing introduced a more cautionary stance towards GM crops in the late 1990s. A 2002 ban on foreign investment in the local GM seed industry has set back efforts by international biotechnology firms to develop a foothold in this potentially lucrative market. Nonetheless, public funding to the biotechnology sector increased in the late 1990s, and promoting genetic engineering as a key instrument of food security policy.

Approved biotechnology products

The following is a list of food products that have been approved for commercial production by China. The list does not include the petunia events that have been approved nor animal vaccine events that have also received approval.

Ag GMOs approved for commercial production in China (as of March 1, 2005)

Crop	Trait	Developer	Event	Commercial production area	Validity
Cotton	Insect resistance	Monsanto	NC33B	Hebei, Shandong	2003-2007
Cotton	Insect resistance	Biotech Research Institute, CAAS	Bt cotton	Shanxi, Anhui, Shandong, Hubei	N/A
Cotton	Insect resistance	Monsanto	NC32B	Anhui	2000-2004
Cotton	Insect resistance	Monsanto	PM1560BG	Anhui	2000-2004
Cotton	Insect resistance	Biotech Research Institute, CAAS	SGK321	Anhui, Hebei, Henan, Shandong, Shanxi	1999-2004, 2002-2005
Cotton	Insect resistance	Biotech Research Institute, CAAS	GK1	Anhui	2003-2007
Cotton	Insect resistance	Monsanto	DP410B	Anhui, Henan, Hubei, Hunan, Jiangsu, Jiangxi, Sichuan	2003-2007
Sweet pepper	Virus resistance	Beijing University	PK-SP01	Beijing, Fujian, Yunnan	1999-2004
Sweet pepper	Virus resistance	Beijing University	PK-TM8805R	Beijing, Fujian, Yunnan	1999-2004
Tomato	Long shelf life	Microorganism Research Institute, CAS	Da Dong No. 9	Beijing	2000-2004
Cotton	Insect resistance	Biotech Research Institute, CAAS	GK-12	Hebei, Henan, Jiangsu, Shandong, Xinjiang	1999-2004

Cotton	Insect resistance	Biotech Research Institute, CAAS	GK91-5	Hebei, Henan, Liaoning, Shanxi, Xinjiang	1999-2004, 2003-2007
Cotton	Insect resistance	Monsanto	DP99B	Hebei, Henan, Shandong	2003-2007
Cotton	Insect resistance	Biotech Research Institute, CAAS	SGK-23	Henan, Shandong, Anhui, Hebei	2003-2007
Cotton	Insect resistance	Biotech Research Institute, CAAS	SGK-27	Henan, Hebei, Anhui, Hubei, Shandong	2003-2007
Cotton	Insect resistance	Biotech Research Institute, CAAS/Cotton Research Institute, CAAS	SGKz4	Henan, Shandong	2004-2008
Cotton	Insect resistance	Biotech Research Institute, CAAS	GK19	Hubei, Xinjiang	2003-2007, 2002-2005
Cotton	Insect resistance	Biotech Research Institute, CAAS	GK22	Jiangsu	2002-2005
Cotton		Microorganism Research Institute, CAS/Cotton Reserch Institute of Shanxi Academy of Ag. Sciences	DR409	Shanxi, Shandong, Henan	2004-2008
Cotton	Insect resistance	Monsanto	DPH37B	Anhui	N/A
Cotton	Insect resistance	Monsanto	NC20B	Henan	N/A
Cotton	Insect resistance	Biotech Research Institute, CAAS/Shandong Cotton Research Center	GK30	Shandong, Henan	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Shandong Cotton Research Center	GK31	Shandong	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Shandong Cotton Research Center	GK32	Shandong, Jiangsu	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Shandong Cotton Research Center	GK33	Henan, Shandong	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Shandong Cotton Research Center	GK34	Shandong	

Cotton	Insect resistance	Biotech Research Institute, CAAS/Shandong Cotton Research Center	GK35	Shandong	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Hebei Hejian Guoxin Rural Extension Service	GK39	Hebei, Henan	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Hebei Hejian Guoxin Rural Extension Service	GK44	Henan	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Hebei Handan Research Institute of Ag. Sciences	GK45	Henan, Hebei	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Jiangsu Siyang	GK51	Anhui (Huainan), Jiangsu	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Shandong Cotton Research Center	GK52	Shandong	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Jiangsu Dafeng Cotton Breeding Farm	GK58	Jiangsu	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Shandong Lunan Ag Extension Service	GKz1	Henan, Shaanxi	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Shandong Lunan Ag Extension Service	GKz2	Henan, Shaanxi	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Shandong Lunan Ag Extension Service	GKz8	Hubei, Jiangsu	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Shandong Cotton Research Center	GKz10	Jiangsu, Shandong	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Hebei Handan Research Institute of Ag	GKz11	Hebei, Henan	

Cotton	Insect resistance	Biotech Research Institute, CAAS/Shandong Cotton Research Center	GKz12	Jiangsu, Shandong	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Shandong General Seed Station	GKz13	Jiangsu, Shandong	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Hunan Cotton Science Research Institute	GKz17	Hubei, Hunan	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Zhejiang Cixi Academy of Ag Sciences	GKz18	Jiangxi, Zhejiang	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Hebei Academy of Ag & Forestry Sciences	GKz19	Hebei, Henan	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Jiangsu Keteng Cotton Co. Ltd	GKz20	Jiangsu	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Hebei Hejian Guoxin Ag Extension Service	GKz21	Hebei, Henan	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Shandong Cotton Science System Engineering Co.	GKz22	Shandong	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Nanjiang Agricultural University	GKz23	Anhui, Hubei	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Shandong Cotton Research Center	GKz25	Anhui, Shandong	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Shandong Cotton Research Center	GKz26	Jiangsu, Shandong	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Jiangsu Academy of Ag Sciences	GKz27	Hubei, Jiangsu	

Cotton	Insect resistance	Biotech Research Institute, CAAS/Shandong Cotton Research Center	GKz29	Jiangsu, Shandong	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Jiangsu Yancheng Xinyang Ag Experiment Station	GKz32	Jiangsu	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Hubei Huimin Seed Co.	GKz33	Hubei	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Sichuan Academy of Ag Sciences	GKz34	Sichuan	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Shandong Jiyang Luyou Cotton Institute	GKz39	Jiangsu, Shandong,	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Hebei Handan Academy of Ag Sciences	GKz41	Hebei, Henan	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Cotton Research Institute, CAAS	GKz(zhong)39	Henan, Shandong, Anhui	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Cotton Research Institute, CAAS	RH- 5	Anhui, Henan, Shandong	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Hebei Hejian Guoxin Ag Extension Service	sGK3	Hebei, Shandong	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Beijing Silver Land Biotech Co.	sGK10	Hebei, Henan	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Beijing Silver Land Biotech Co.	sGK11	Hebei, Henan	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Henan Xinxiang Jinke Cotton Research Institute	SGK36	Hebei, Henan	

Cotton	Insect resistance	Biotech Research Institute, CAAS/Beijing Silver Land Biotech Co.	SGK35	Henan	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Cotton Research Institute, CAAS	sGK156	Anhui, hebei, Henan, Shandong	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Cotton Research Institute, CAAS	sGK3017	Anhui, Hebei, Henan, Shandong	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Nanjing Ag University	sGKz2	Henan, Jiangsu	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Cotton Research Institute, CAAS	sGKz4	Anhui, Hubei	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Hebei Handan Academy of Ag. Scieices	sGKz6	Hebei, Henan	
Cotton	Insect resistance	Institute, CAAS/Beijing Silver Land Biotech Co.	sGKz8	Hebei, Shandong	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Jiangsu Academy of Ag Sciences	sGKz9	Anhui, Jiangsu	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Cotton Research Institute, CAAS	SGKz980	Anhui, Henna,	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Cotton Research Institute, CAAS	SGKz2018	Anhui, Henan, Hubei, Shandong	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Cotton Research Institute, CAAS	SGKzBZ12	Anhui, Henan, Hubei, Shandong	

Biotechnology products under field trials

China allows and requires field-testing of biotechnology crops targeted for cultivation. Permission for all testing and final issuance of a safety certificate is handled by the Ministry of Agriculture's Biosafety Office or Agricultural GMO. After passing "medium testing," defined as "small-scale experiments conducted in a controlled system or under controlled conditions," China requires applicants to go through two field-tests before being approved for a safety certificate. The first test is the "environmental release" test, defined as "medium-scale experiments conducted under natural conditions with proper safety protection." This is

followed by the "production testing," which is carried out on a large-scale prior to production and application. Industry states this process of bringing a product to market for cultivation takes eight to ten years if there are no serious problems.

China does not regularly publish a list of products under development. Information from the Ministry of Science and Technology indicates that since 2001 China has initiated 333 limited field tests and 158 enlarged field tests of biotechnology products.

Stacked events and simultaneous approvals

At the moment China's regulations do not touch on stacked events and thus no formal approval process for stacked events exists. China has approved cases of stacked events for local cultivation and officials have indicated that China will consider approval for importation of products with stacked events for processing on a case-by-case basis. China has not decided how it will regulate this area in the future. China also does not allow simultaneous approvals in the U.S. and China. China currently requires approvals to be undertaken in the home country before approval can be sought in China.

Labeling policy for biotechnology products

China's labeling regulations, governed by Ministry of Agriculture Decree 10 (CH2002), require agricultural biotech products listed in the regulations be labeled and prohibits the importation and sale of any unlabeled or mislabeled products. The listed products are:

1. Soybean seed, soybean, soybean powder, soybean oil and soybean meal;
2. Corn seeds, corn, corn oil and corn powder;
3. Rape seed for planting, rape seed, rape oil and rape meal;
4. Cotton seed;
5. Tomato seed, fresh tomato and tomato jam.

Decree 10 states the reason for the regulation is "to strength the administration of Ag GMO labeling, standardize the selling activities of Ag GMOs, guide the production and consumption of Ag GMOs and protect consumers' right to be informed." The regulations spell out the type of labeling required as well as the specific language that is required on the individual labels.

China and the Biosafety Protocol

China's State Council ratified the Biosafety Protocol on April 27, 2005. This was not in time for the 2nd Meeting of the Parties (MOP) in Montreal, thus China participated as an observer. China is expected to be an active and influential participant in the MOP-3 meetings taking place in March 2006 in Brazil.

As the lead authority for the Biosafety Protocol, China's State Environmental Protection Agency (SEPA) is charged with developing implementing regulations. Though SEPA has not published any new or revised laws with regard to implementation of the Protocol, SEPA has continued to state its intent to develop an overarching Biosafety Law that would take precedence over the Ministry of Agriculture's decrees regulating agricultural biotechnology.

Barriers to U.S. exports of biotechnology products

Several barriers to U.S. exports of biotechnology products to China include:

No simultaneous approvals: China requires U.S. regulatory approval for a product before a product may apply for approval in China. This system makes it impossible to apply simultaneously in both markets and thus causes a delay on bringing U.S. agricultural biotechnology products to the Chinese market.

Windows for submission: China has only two windows a year when companies can submit applications for new products, once in March and another in September.

Lack of clarity on stacked events: China has not yet developed policy on stacked events, and no formal approval process for stacked events exists. China has approved cases of stacked events for local cultivation and officials have indicated that China will consider approval for importation of products with stacked events for processing on a case-by-case basis. Lack of clarity in this area is a concern of industry.

Duplicated testing for imports: When goods are being approved for import to China they must first prove they have been approved by their host country. They are then required to undergo similar tests in China before being approved for a safety certificate. The extra testing in China means a delay of one to two years when bringing a product to market.

SECTION IV. MARKETING ISSUES

Market acceptance issues

China's consumers are by and large open to and acceptant of agricultural biotechnology products. Generally, there does not seem to be a negative stigma attached to biotech foods as exists in some other Asian markets. A recent nation-wide joint study by Lin, Somwaru and Tuan of USDA's Economic Research Service and Huang and Bai of the Chinese Academy of Sciences' Center for Chinese Agricultural Policy found about 60 percent or higher of respondents were willing to purchase biotech foods (including soy beans and rice) without any price discrimination. Thus, these consumers would not differentiate between biotech and non-biotech foods when at a marketplace if the prices were equal. Another 20 percent would only buy biotech food when a price discount was offered. Finally another 20 percent of respondents to the study would not accept biotech foods (with the exception of neutraceutical biotech rice) regardless of any discounts in price.

Another study by the same group found that Chinese consumers' awareness to biotech foods was low, with about 75 percent having never heard of biotech foods or having heard of them on an occasional basis. The study found that a great majority of Chinese consumers favorable or neutral attitude toward biotech foods, with only 5-15 percent of urban consumers opposed to biotech foods.

These findings seem consistent with a recent study by the Asian Food Information Centre's study on communicating with consumers on biotechnology that found that a "majority of consumers adopted an open-minded position towards biotechnology foods and did not reject them per se."

SECTION V. CAPACITY BUILDING AND OUTREACH

U.S. Government funded outreach and capacity building programs

The U.S. and China are working closely on several fronts to assist China in its capacity to effectively and fairly handle its biotechnology sector. The U.S.- China High-Level Biotechnology Joint Working Group (BWG) was established in July 2002 as a way to address bilateral biotechnology issues of mutual interest. To supplement the policy discussions, a technical subgroup (TWG) was established in July 2003. Together, this forum has become a constructive means by which the U.S. and China regularly engage to address issues of concern.

During the 5th BWG held in Beijing on August 15-16, the U.S. and China signed a memorandum of understanding to undertake a biotechnology capacity building initiative funded by the U.S. Trade and Development Agency.

Some technical cooperation programs agreed to at the last BWG are a Technical Workshop on Safety Assessment, a Sampling/Testing Expert Exchange, a Veterinary Biologics visit in Iowa, a Biotechnology Short Course, an Insect Resistance Management Collaboration, other research collaborations, APEC support and future technical meetings.

SECTION VI. REFERENCE MATERIALS

Reference Materials Subcategory

For more on studies on the marketing of biotechnology products, please see "Consumer Attitudes Toward Biotech Foods in China" by W. Lin, A. Somwaru and F. Tuan of the Economic Research Service of the U.S. Department of Agriculture and J. Huang and J. Bai of the Center for Chinese Agricultural Policy of the Chinese Academy of Sciences. The study is a selected

paper prepared for presentation at the American Agricultural Economics Association Annual Meeting in Denver, Colorado on August 1-4, 2004.

A second study by the same authors titled "Consumers' Willingness to Pay for Biotech Foods in China" was prepared for presentation at the American Agricultural Economics Association Annual Meeting in Providence, RI and is dated May 12, 2005.

Yet another study on the market in China is the Asian Food Information Centre's "Communicating with Consumers on Food Biotechnology," prepared in May of 2005. The survey tracks consumer views on biotech foods from a variety of angles. The report looks at China, India, and the Philippines.

Other useful sources for information are:

USDA GAIN Reports: <http://www.fas.usda.gov/scriptsw/attacherep/default.asp>

The International Service for the Acquisition of Agri-biotech Applications: www.isaaa.org